IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

APPLICANT:	**Yamanouchi Pharmaceutical Co., Ltd.**	
		DATE: December 20, 2004
U.S. PATENT NO.:	**6,017,927**	
ISSUED:	**January 25, 2000**	

Application for Extension of
Patent Term Pursuant to 35 U.S.C. § 156

Mail Stop: Patent Extension
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Yamanouchi Pharmaceutical Co., Ltd ("Yamanouchi" or "the Applicant"), Assignee of the above-identified patent, hereby petitions for extension of U.S. Patent No. 6,017,927 pursuant to 35 U.S.C. § 156(d) and 37 C.F.R. § 1.740, and states in part thereof as follows:

(1) **A COMPLETE IDENTIFICATION OF THE APPROVED PRODUCT AS BY APPROPRIATE CHEMICAL AND GENERIC NAME, PHYSICAL STRUCTURE OR CHARACTERISTICS.**

The United States Food and Drug Administration ("FDA") has approved a New Drug Application ("NDA") (NDA # 21-518) for a human drug product, i.e., VESIcare® (solifenacin succinate) film-coated tablet (hereinafter "Product"), which is effective for relief of symptoms of urinary frequency, urinary urgency or urinary incontinence associated with overactive bladder. The chemical name of solifenacin is:

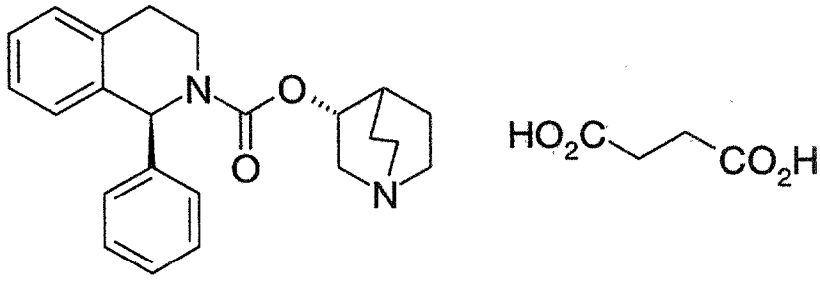
(+)-(1S,3'R)-quinuclidin-3'-yl 1-phenyl-1,2,3,4-tetrahydroisoquinoline-2-carboxylate

(1*S*)-(3*R*)-1-azabicyclo[2.2.2]oct-3-yl 3,4-dihydro-1-phenyl-2(1*H*)-isoquinolinecarboxylate; or

(3*R*)-3-quinuclidinyl (1*S*)-1-phenyl-1,2,3,4-tetrahydro-2- isoquinolinecarboxylate; or

(3*R*)-1-azabicyclo[2.2.2]oct-3yl (1*S*)-1-phenyl-3,4-dihydroisoqunoline -2(1*H*)-carboxylate.

with a molecular formula of $C_{23}H_{26}N_2O_2 \cdot C_4H_6O_4$, a molecular weight of 480.56, and a structural fomula of:



(2) **A COMPLETE IDENTIFICATION OF THE FEDERAL STATUTE INCLUDING THE APPLICABLE PROVISION OF LAW UNDER WHICH THE REGULATORY REVIEW OCCURRED.**

The regulatory review occurred under § 505 of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), 21 U.S.C. § 355.

(3) **AN IDENTIFICATION OF THE DATE ON WHICH THE PRODUCT RECEIVED PERMISSION FOR COMMERCIAL MARKETING OR USE UNDER THE PROVISION OF LAW UNDER WHICH THE APPLICABLE REGULATORY REVIEW PERIOD OCCURRED.**

FDA approved NDA #21-518 for VESIcare® (solifenacin succinate) film-coated tablet for commercial marketing under § 505(b) of the FDC Act on November 19, 2004.

(4) **IN THE CASE OF A DRUG PRODUCT, AN IDENTIFICATION OF EACH ACTIVE INGREDIENT IN THE PRODUCT AND AS TO EACH ACTIVE INGREDIENT, A STATEMENT THAT IT HAS NOT BEEN PREVIOUSLY APPROVED FOR COMMERCIAL MARKETING OR USE UNDER THE FDC ACT, THE PUBLIC HEALTH SERVICE ACT, OR THE VIRUS-SERUM-TOXIN ACT, OR A STATEMENT OF WHEN THE ACTIVE INGREDIENT WAS APPROVED FOR COMMERCIAL MARKETING OR USE (EITHER ALONE OR IN COMBINATION WITH OTHER ACTIVE**

INGREDIENTS), THE USE FOR WHICH IT WAS APPROVED, AND THE PROVISION OF LAW UNDER WHICH IT WAS APPROVED.

The only active ingredient in the Product (which is a human drug) is solifenacin succinate. FDA has not previously approved solifenacin succinate for commercial marketing or use under the FDC Act, the Public Health Service Act, or the Virus-Serum-Toxin Act.

(5) **A STATEMENT THAT THE APPLICATION IS BEING SUBMITTED WITHIN THE SIXTY DAY PERIOD PERMITTED FOR SUBMISSION PURSUANT TO 37 C.F.R. § 1.720(f) AND AN IDENTIFICATION OF THE DATE OF THE LAST DAY ON WHICH THE APPLICATION COULD BE SUBMITTED.**

FDA approved the Product on November 19, 2004. The last day within the sixty-day period permitted for submission of an application for extension of a patent is January 18, 2005. This application is being submitted before January 18, 2005.

(6) **A COMPLETE IDENTIFICATION OF THE PATENT FOR WHICH AN EXTENSION IS BEING SOUGHT BY THE NAME OF THE INVENTOR, THE PATENT NUMBER, THE DATE OF ISSUE, AND THE DATE OF EXPIRATION.**

The patent for which an extension is being sought is U.S. Patent No. 6,017,927, which issued on January 25, 2000 to Makoto Takeuchi, Ryo Naito, Masahiko Hayakawa, Yoshinori Okamoto, Yasuhiro Yonetoku, Ken Ikeda, and Yasuo Isomura, and which is assigned to Yamanouchi Pharmaceutical Co., Ltd. The assignment was recorded in the USPTO on August 28, 1997, at reel 008827, frame 0376. A copy of the assignment of the patent to Yamanouchi is attached hereto as Attachment 1. U.S. Patent No. 6,017,927 is scheduled to expire on December 27, 2015.

(7) **A COPY OF THE PATENT FOR WHICH AN EXTENSION IS BEING SOUGHT, INCLUDING THE ENTIRE SPECIFICATION (INCLUDING CLAIMS) AND DRAWINGS.**

A copy of U.S. Patent No. 6,017,927 is attached hereto as Attachment 2.

(8) **A COPY OF ANY DISCLAIMER, CERTIFICATE OF CORRECTION, RECEIPT OF MAINTENANCE FEE PAYMENT, OR REEXAMINATION CERTIFICATE ISSUED IN THE PATENT.**

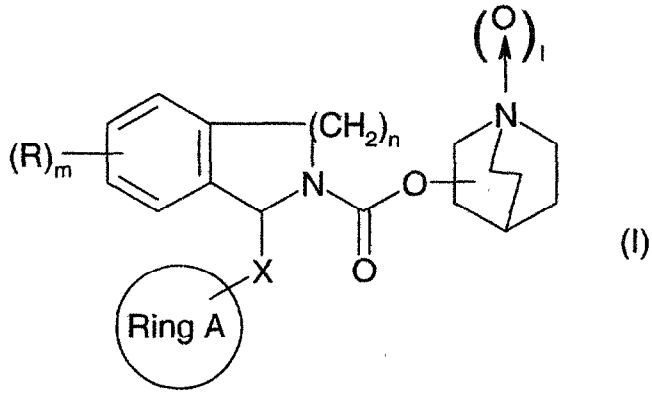
There are no disclaimers or reexamination certificates. Certificates of correction and a maintenance fee payment receipt are attached hereto as Attachments 3A, 3B, and 3C.

(9) **A STATEMENT THAT THE PATENT CLAIMS THE APPROVED PRODUCT, OR A METHOD OF USING OR MANUFACTURING THE APPROVED PRODUCT, AND A SHOWING WHICH LISTS EACH APPLICABLE PATENT CLAIM AND DEMONSTRATES THE MANNER IN WHICH AT LEAST ONE SUCH PATENT CLAIM READS ON THE APPROVED PRODUCT .**

U.S. Patent No. 6,017,927 claims the Product and also claims a composition of matter comprising the drug product.

Claim 1

A quinuclidine derivative represented by the following formula (I):



(I)

where the symbols in the formula have the following meanings: Ring A:

(1) an aryl group having 6 to 14 carbon atoms

(3) a cycloalkyl group having 3 to 8 carbon atoms

(4) a cycloalkenyl group having 3to 8 carbon atoms;

wherein groups (1) to (5) above may be unsubstituted or substituted by one or more substituents selected from the group consisting of a halogen atom, a hydroxyl group, a lower alkoxy group, a carboxyl group, a lower alkoxycarbonyl group, a lower acyl group,

a mercapto group, a lower alkylthio group, a sulfonyl group, a lower alkylsulfonyl group, a sulfinyl group, a lower alkylsulfinyl group, a sulfonamido group, a lower alkanesulfonamido group, a carbamoyl group, a thiocarbamoyl group, a mono- or di-lower aklylcarbamoyl group, a nitro group, a cyano group, an amino group, a mono- or di-lower alkylamino group, a methylenedioxy group, an ethylenedioxy group, and a lower alkyl group which may be substituted by a halogen atom, a hydroxyl group, a lower alkoxyl group, an amino group or mono- or di-lower alkylamino group

X: a single bond or a methylene group;

R: a halogen atom, a hydroxyl group, a lower alkoxy group, a carboxyl group, a lower alkoxycarbonyl group, a lower acyl group, a mercapto group, a lower alkylthio group, a sulfonyl group, a lower alkylsulfonyl group, a sulfinyl group, a lower alkylsufinyl group, a sulfonamido group, a lower alkanesulfonamido group, a carbamoyl group, a thiocarbamoyl group, a mono- or di-lower alkylcarbamoyl group, a nitro group, a cyano group, an amino group, a mono- or di-lower alkylamino group, a methylenedioxy group, an ethylenedioxy group or a lower alkyl group which may be substituted by a halogen atom, a hydroxyl group, a lower alkoxy group, an amino group or a mono- or di-lower alkylamino group;

l: 0 or 1;

m: 0 or an integer of 1 to 3, and

n: an integer of 1 or 2,

a salt thereof, an N-oxide thereof, or a quaternary ammonium salt thereof.

Claim 2

The quinuclidine derivative, a salt thereof, or a quaternary ammonium salt thereof according to claim 1, wherein R represents a halogen atom, a lower alkyl group, a hydroxyl group, a lower alkoxy group, a nitro group, a cyano group, an amino group or a mono- or di-lower alkylamino group, and the ring A represents an aryl group having 6 to 14 carbon atoms, a cycloalkyl group having 3 to 8 carbon atoms or a cycloalkenyl group having 3 to 8 carbon atoms, in which said ring may be substituted by a halogen atom, a lower alkyl group, a hydroxyl group, a lower alkoxyl group, a nitro group, a cyano group, an amino group or a mono- or di-lower alkylamino group.

Claim 3

The quinuclidine derivative, a salt thereof, or a quaternary ammonium salt thereof according to claim 2, wherein m is 0, and the ring A represents an aryl group, a cycloalkyl group or a cycloalkenyl group which may be substituted by a halogen atom, a

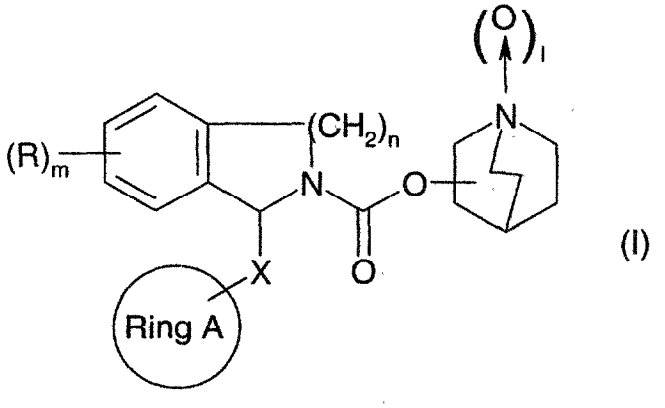
lower alkyl group, a hydroxyl group or a lower alkoxy group.

Claim 4
The quinuclidine derivative, a salt thereof, or a quaternary ammonium salt thereof according to claim 3, wherein the ring A represents a phenyl group which may be substituted by a halogen atom or a lower alkyl group, or cycloalkyl group.

Claim 5
The quinuclidine derivative, a salt thereof, or a quaternary ammonium salt thereof according to any one of claims 2 to 4, wherein X represents a single bond.

Claim 6
A quinuclidine derivative, a salt thereof, or a quaternary ammonium salt thereof according to any one of claim 1, which is selected from the group consisting of 3-quinuclidinyl 1-phenyl-1,2,3,4-tetrahydro-2-isoquinolinecarboxylate, 3-quinuclidinyl 1-(4-chlorophenyl)-1,2,3,4-tetrahydro-2-isoquinolinecarboxylate, 3-quinuclidinyl 1-(4-fluorophenyl)-1,2,3,4-tetrahydro-2-isoquinolinecarboxylate, 3-quinuclidinyl 1,2,3,4-tetrahydro-1-(4-tolyl)-2-isoquinolinecarboxylate, and 3-quinuclidinyl 1-cyclohexyl-1,2,3,4-tetrahydro-2-isoquinolinecarboxylate.

Claim 7
A pharmaceutical composition which comprises a quinuclidine derivative represented by the following formula (I):



(I)

where the symbols in the formula have the following meanings: Ring A:

(1) an aryl group having 6 to 14 carbon atoms

(3) a cycloalkyl group having 3 to 8 carbon atoms

(4) a cycloalkenyl group having 3 to 8 carbon atoms;

wherein groups (1) to (5) above may be unsubstituted or substituted by one or more substituents selected from the group consisting of a halogen atom, a hydroxyl group, a lower alkoxy group, a carboxul group, a lower alkoxycarbonyl group, a lower acyl group, a mercapto group, a lower alkylthio group, a sulfonyl group, a lower alkylsulfonyl group, a sulfinyl group, a lower alkylsulfinyl group, a sulfonamido group, a lower alkanesulfonamido group, a carbamoyl group, a thiocarbamoyl group, a mono- or di-lower aklylcarbamoyl group, a nitro group, a cyano group, an amino group, a mono- or di-lower alkylamino group, a methylenedioxy group, an ethylenedioxy group and a lower alkyl group which may be substituted by a halogen atom, a hydroxyl group, a lower alkoxyl group, an amino group or mono- or di-lower alkylamino group

X: a single bond or a methylene group;

R: a halogen atom, a hydroxyl group, a lower alkoxy group, a carboxyl group, a lower alkoxycarbonyl group, a lower acyl group, a mercapto group, a lower alkylthio group, a sulfonyl group, a lower alkylsulfonyl group, a sulfinyl group, a lower alkylsufinyl group, a sulfonamido group, a lower alkanesulfonamido group, a carbamoyl group, a thiocarbamoyl group, a mono- or di-lower alkylcarbamoyl group, a nitro group, a cyano group, an amino group, a mono- or di-lower alkylamino group, a methylenedioxy group, an ethylenedioxy group or a lower alkyl group which may be substituted by a halogen atom, a hydroxyl group, a lower alkoxy group, an amino group or a mono- or di-lower alkylamino group;

l: 0 or 1;

m: 0 or an integer of 1 to 3, and

n: an integer of 1 or 2, or
a salt thereof, an N-oxide thereof, or a quaternary ammonium salt thereof,
and a pharmaceutically acceptable carrier.

The applicable patent claims which read on the Product are Claims 1,2,3,4,5,6 and 7.

Claim 1 reads on the Product because the Product is the succinate of the (+) optically active isomer of (1S,3'R)-quinuclidin-3'-yl 1-phenyl-1,2,3,4-tetrahydroisoquinoline-2-carboxylate which is a compound of the formula of Claim 1 wherein Ring A is a phenyl group, which is (1) an aryl group having 6 to 14 carbon atoms, X is a single bond, l is 0, m is 0, n is 2 and R does not exist, because m is 0.

Claim 2 reads on the Product because the Product is the succinate of the (+) optically active isomer of (1S,3'R)-quinuclidin-3'-yl 1-phenyl-1,2,3,4-tetrahydroisoquinoline-2-carboxylate which is a compound of Claim 1 wherein Ring A is a phenyl group, which is an aryl group having 6 to 14 carbon atoms and R does not exist, because m is 0.

Claim 3 reads on the Product because the Product is the succinate of the (+) optically active isomer of (1S,3'R)-quinuclidin-3'-yl 1-phenyl-1,2,3,4-tetrahydroisoquinoline-2-carboxylate which is a compound of Claim 2 wherein m is 0, Ring A is a phenyl group, which is an aryl group.

Claim 4 reads on the Product because the Product is the succinate of the (+) optically active isomer of (1S,3'R)-quinuclidin-3'-yl 1-phenyl-1,2,3,4-tetrahydroisoquinoline-2-carboxylate which is a compound of Claim 3 wherein Ring A is a phenyl group.

Claim 5 reads on the Product because the Product is the succinate of the (+) optically active isomer of (1S,3'R)-quinuclidin-3'-yl 1-phenyl-1,2,3,4-tetrahydroisoquinoline-2-carboxylate which is a compound of any one of Claims 2 to 4 wherein X is a single bond.

Claim 6 reads on the Product because the Product is the succinate of the (+) optically active isomer of the compound specifically named in Claim 6.

Claim 7 reads on the Product because the Product is a pharmaceutical composition which comprises the succinate of the (+) optically active isomer of (1S,3'R)-quinuclidin-3'-yl 1-phenyl-1,2,3,4-tetrahydroisoquinoline-2-carboxylate which is a compound of the formula of Claim 7 wherein Ring A is a phenyl group, which is (1) an aryl group having 6 to 14 carbon atoms, X is a single bond, l is 0, m is 0, n is 2 and R does not exist, because m is 0.

(10) A STATEMENT BEGINNING ON A NEW PAGE OF THE RELEVANT DATES AND INFORMATION PURSUANT TO 35 U.S.C. 156(g) IN ORDER TO ENABLE THE SECRETARY OF HEALTH AND HUMAN SERVICES OR THE SECRETARY OF AGRICULTURE, AS APPROPRIATE, TO DETERMINE THE APPLICABLE REGULATORY REVIEW PERIOD.

The relevant dates and information pursuant to 35 U.S.C. § 156(g) needed to enable the Secretary of Health and Human Services to determine the applicable regulatory review period are as follows:

The Investigational New Drug Application ("IND") for the Product became effective on May 5, 1999 (IND #58,135).

New Drug Application ("NDA") #21-518 was submitted to FDA on December 19, 2002.

FDA approved NDA #21-518 on November 19, 2004.

(11) A BRIEF DESCRIPTION BEGINNING ON A NEW PAGE OF THE SIGNIFICANT ACTIVITIES UNDERTAKEN BY THE MARKETING APPLICANT DURING THE APPLICABLE REGULATORY REVIEW PERIOD WITH RESPECT TO THE APPROVED PRODUCT AND THE SIGNIFICANT DATES APPLICABLE TO SUCH ACTIVITIES.

DATE TO FDA	DESCRIPTION
02 Apr. 1999	Initial IND Application
17 Jun. 1999	Protocol Amendment Information Amendment: Pharm/Tox
09 Dec. 1999	Information Amendment: Clinical
03 March 2000	Protocol Amendment
12 Apr. 1999	Information Amendment: Pharm/Tox; Clinical Protocol Amendment
30 June 2000	Annual Report
01 Sept. 2000	Protocol Amendment
14 Sept. 2000	Information Amendments: Chemistry, Pharm/Tox, Clinical
18 Oct. 2000	Protocol Amendment: Updated Investigators Brochure
16 Nov. 2000	Protocol Amendment
05 Dec. 2000	Information Amendment
21 Dec. 2000	Information Amendment: Toxicology, Chemistry
01 Feb. 2001	Protocol Amendment
16 Feb. 2001	Request for Comment
21 February 2001	Information Amendment
27 February 2001	Protocol Amendment
21 March 2001	Protocol Amendment
09 April 2001	Protocol Amendment
03 May 2001	Protocol Amendment
30 May 2001	Protocol Amendment
01 June 2001	Information Amendment
18 June 2001	Protocol Amendment
29 June 2001	Annual Report
05 July 2001	Information Amendments
13 July 2001	Information Amendment
17 July 2001	Protocol Amendment
14 August 2001	Protocol Amendment
17 August 2001	Protocol Amendment
19 September 2001	Protocol Amendment
28 September 2001	Protocol Amendment
19 October 2001	Protocol Amendments
01 November 2001	Protocol Amendments

DATE TO FDA	DESCRIPTION
09 November 2001	Other Amendment: Statistical Analysis Plan
06 December 2001	Protocol Amendment
21 January 2002	Protocol Amendment
25 January 2002	Other Amendment
29 January 2002	Other Amendment
13 February 2002	Protocol Amendment
14 February 2002	Other Amendment
15 February 2002	Other Amendment
18 February 2002	Other Amendment
26 February 2002	Other Amendment
06 March 2002	Other Amendment
14 March 2002	Information Amendment: Pharmacology/Toxicology, Clinical
22 March 2002	Other Amendment: Investigator's Brochure
11 June 2002	Protocol Amendment
01 July 2002	Annual Report
06 August 2002	Protocol Amendment
27 August 2002	Other Amendment
25 September 2002	Other Amendment
30 September 2002	Other Amendment
19 December 2002	New Drug Application #21-518
24 January 2003	Protocol Amendment
19 February 2003	Protocol Amendments
27 February 2003	Information Amendment
26 March 2003	NDA Field Copy Submission
03 April 2003	Information Amendment
11 April 2003	Information Amendment
25 April 2003	4-Month safety update
06 May 2003	Protocol Amendment
08 May 2003	CMC Amendment
13 May 2003	Information Amendment
13 June 2003	CMC Amendment
16 June 2003	Clinical Amendment
26 June 2003	Information Amendment
15 July 2003	Information Amendment
28 July 2003	Information Amendment
25 August 2003	Information Amendment
29 August 2003	Information Amendment
11 September 2003	Information Amendment
19 September 2003	Draft Labeling
22 September 2003	Information Amendment

DATE TO FDA	DESCRIPTION
26 September 2003	Response to FDA Request for Information
03 October 2003	Response to FDA Request for Information
09 October 2003	Response to FDA Request for Information
15 October 2003	Response to FDA Request for Information
16 October 2003	Response to FDA Request for Information
20 October 2003	Response to FDA Approvable Letter
11 November 2003	Protocol Amendment
09 December 2003	Information Amendment
24 March 2004	Response to FDA Request for Information
18 May 2004	Complete Response to Approvable Letter of October 17, 2003
18 June 2004	Clinical Amendment
17 September 2004	Information Amendment
24 September 2004	Information Amendment
30 September 2004	Information Amendment
29 October 2004	Response to FDA Comments
01 November 2004	Response to FDA Comments
08 November 2004	Response to FDA Comments
17 November 2004	Response to FDA Comments
18 November 2004	Submission of Final Draft Labeling

(12) A STATEMENT BEGINNING ON A NEW PAGE THAT IN THE OPINION OF THE APPLICANT THE PATENT IS ELIGIBLE FOR THE EXTENSION AND A STATEMENT AS TO THE LENGTH OF EXTENSION CLAIMED, INCLUDING HOW THE LENGTH OF EXTENSION WAS DETERMINED.

It is the opinion of Yamanouchi that U.S. Patent No. 6,017,927 is eligible for extension, because: (a) the patent claims the Product or a method of using the Product; (b) the term of the patent has never been extended; (c) this application is submitted in compliance with all requirements of 37 C.F.R. § 1.740; (d) the Product has been subject to a regulatory review period as defined in 35 U.S.C. § 156(g) before its commercial marketing or use; (e) Yamanouchi has received permission from FDA for commercial marketing or use of the Product and the permission for the commercial marketing or use of the Product is the first received permission for commercial marketing or use under the provision of law under which the applicable regulatory review occurred; (f) this Application for Extension is submitted within the sixty-day period after the Product first received permission for commercial marketing and use; (g) the term of the patent has not expired before submission of this Application for Extension; and (h) no other patent term has been extended for the same regulatory review period for the Product.

Yamanouchi further believes that U.S. Patent No. 6,017,927 is entitled to an extension of 2 years 327 days as determined by the following:

(i) Number of days of the testing phase subsequent to issuance of the patent (January 25, 2000 to December 18, 2002) is 1059 days. The IND for the Product became effective on May 5, 1999, but U.S. Patent No. 6,017,927 issued on January 25, 2000.

(ii) One half of the testing phase is 529 days.

(iii) Number of days in the approval phase (December 19, 2002 to November 19, 2004 is 702 days.

(iv) The sum of (ii) and (iii) is 1,231 days.

(v) The patent was issued after the enactment date of 35 U.S.C. § 156, September 24, 1984, and the IND and NDA for the Product were filed subsequent to that date. Therefore, the term of the patent may only be extended for up to five years under 35 U.S.C. § 156(g)(1)(B) and 35 U.S.C. § 156(g)(6)(A).

(vi) The patent term extension is also subject, under 35 USC 156(c)(3), to the fourteen year limitation as to the net effective life of the patent after the NDA approval. This limitation dictates that the subject patent cannot be extended beyond November 19, 2018. Adding 1,231 days to the term of the

patent remaining after the date of NDA approval of the Product exceeds fourteen years.

(vii) In light of the above, the extended expiration date of the subject patent is believed to be November 19, 2018, namely 2 years and 327 days after the date of the current patent term expiration (fourteen years after the date of NDA approval).

(13) **A STATEMENT THAT APPLICANT ACKNOWLEDGES A DUTY TO DISCLOSE TO THE COMMISSIONER OF PATENTS AND TRADEMARKS AND THE SECRETARY OF HEALTH AND HUMAN SERVICES OR THE SECRETARY OF AGRICULTURE ANY INFORMATION WHICH IS MATERIAL TO THE DETERMINATION OF ENTITLEMENT TO THE EXTENSION SOUGHT.**

Yamanouchi acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services any information that is material to any determinations to be made relative to this Application for Extension.

(14) **THE PRESCRIBED FEE FOR RECEIVING AND ACTING UPON THE APPLICATION FOR EXTENSION.**

Please charge deposit account number 194880 in the amount of $1,120.00.

(15) **THE NAME, ADDRESS, AND TELEPHONE NUMBER OF THE PERSON TO WHOM INQUIRIES AND CORRESPONDENCE RELATING TO THE APPLICATION FOR PATENT TERM EXTENSION ARE TO BE DIRECTED.**

Inquiries and correspondence relating to this Application for Extension should be directed to:

Susan J. Mack
Sughrue Mion, PLLC
2100 Pennsylvania Ave., N.W.
Washington, D.C. 20037-3213
T: 202-293-7060
F: 202-293-7860
Email: smack@sughrue.com

(16) FOUR ADDITIONAL COPIES OF THE APPLICATION PAPERS

Four additional copies of the application are attached hereto as Attachment 4.

By: Susan J Mack

Susan J. Mack
Registration Number 30,951

Date: December 20, 2004